

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

COMMONWEALTH OF PENNSYLVANIA and
STATE OF NEW JERSEY,

Plaintiffs,

v.

No. 2:17-cv-04540-WB

DONALD J. TRUMP, *in his official capacity as President of the United States*; ALEX M. AZAR II, *in his official capacity as Secretary of Health and Human Services*; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; STEVEN T. MNUCHIN, *in his official capacity as Secretary of the Treasury*; UNITED STATES DEPARTMENT OF THE TREASURY; EUGENE SCALIA, *in his official capacity as Secretary of Labor*; UNITED STATES DEPARTMENT OF LABOR; and UNITED STATES OF AMERICA.

Defendants.

**OPPOSITION TO DEFENDANTS' MOTIONS FOR SUMMARY JUDGMENT AND
REPLY IN SUPPORT OF STATES' MOTION FOR SUMMARY JUDGMENT**

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INTRODUCTION

Both the Agencies and Littler Sisters trumpet the Supreme Court’s decision that the Agencies may create exemptions from the contraceptive mandate, and may account for potential conflicts with the Religious Freedom Restoration Act (RFRA) when doing so, as if it is conclusive for the issues that remain in this case. But it is not. No matter the scope agency discretion, the exercise of that discretion must reflect reasoned decisionmaking. *Dep’t of Commerce v. New York*, 139 S. Ct. 2551, 2569 (2019). And it must conform to all laws. *FCC v. NextWave Pers. Commc’ns Inc.*, 537 U.S. 293, 300 (2003). The Supreme Court has not assessed the rules at issue in this case against those standards. And held against them, the rules fail.

The Religious Rule, J.A. 1–55, and the Moral Rule, J.A. 56–95, purport to resolve conflicts between the contraceptive mandate and employers’ religious or moral objections to providing that coverage. But the rules sweep far beyond that stated purpose. The Agencies also finalized the two rules without meaningfully engaging with the Agencies’ prior conflicting position on the benefits of contraception and without responding to a medical consensus at odds with the Agencies’ medical conclusions. What is more, the rules violate the Establishment Clause, constitutional and statutory protections against sex-based discrimination, and the direction that the Secretary of Health and Human Services (HHS) not promulgate regulations that impair access to appropriate medical care.

The consequence of the Agencies’ unreasoned rules, and constitutional and statutory violations, is that 126,400 women—and likely more given the Agencies’ flawed methodology for estimating the rules’ effects—are about to lose coverage for care that the Women’s Preventive Services Guidelines (“Guidelines”) deem “necessary for women’s health and well-being.” J.A. 312-A. The remedy for these errors is to vacate the Religious Rule and the Moral Rule.

I. The Rules Are Arbitrary and Capricious

A. The Religious Rule Is Not a Reasonable Solution to Any Conflict between the Contraceptive Mandate and the Religious Freedom Restoration Act

The Supreme Court has ruled that the discretion afforded to the Agencies under the Affordable Care Act's Women's Health Amendment, 42 U.S.C. § 300gg-13(a)(4), allows the Agencies to devise a solution to conflicts between the contraceptive mandate and RFRA, *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2383 (2020). Resolving those conflicts ostensibly was the impetus for the Religious Rule, J.A. 8–13, and so that rule must be reasonably tailored to accomplish that objective, *see Motor Vehicle Mfrs. Ass'n of U.S., Inc., v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983).¹

Yet the scope of the Religious Rule reveals that it cannot reasonably be understood as remedying conflicts with RFRA. The Religious Rule allows entities for which the existing Accommodation resolved any conflict with RFRA still to invoke the new exemption. Entities, including publicly traded corporations, may invoke the new exemption even if compliance with the mandate or Accommodation does not substantially burden their religious exercise and without the Agencies assessing the sincerity of the underlying religious belief. So even if the Religious Rule resolves *some* RFRA violations, *see* Fed. Opp'n at 27; LS Opp'n at 21, these discrepancies, alone and cumulatively, demonstrate that the Religious Rule is not reasonably tailored for that purpose, making it arbitrary and capricious.

To begin, the Religious Rule allows employers for whom the Accommodation resolved any conflict between the mandate and RFRA to remove contraception from their employees'

¹ Little Sisters defends the Agencies' choice to consider conflicts with RFRA while exercising their discretion under the Women's Health Amendment. LS Opp'n at 17-19, ECF No. 255-1. The States have not argued that the Agencies may not consider RFRA violations when exercising their rulemaking authority.

insurance plans anyway. Pls.’ Mem. at 15–16, ECF No. 252-1. This flaw is not about imprecise line drawing, *contra* Fed. Opp’n at 10-11, ECF No. 254-1, but instead reveals a disconnect between the problem the Religious Rule identifies and the solution it creates. The Agencies needed some reasonable explanation why employers for whom the Accommodation resolved any conflict with RFRA may claim the exemption all the same—particularly because the exemption, but not the Accommodation, denies employees coverage for care that the Guidelines still call “necessary for women’s health and well-being.” J.A. 312-A.² Rather than supplying an explanation, the Agencies express confidence that this problem is inconsequential because no entity satisfied with the Accommodation will invoke the exemption. Fed. Opp’n at 11. But the record belies that assurance: The Religious Rule acknowledges that entities content with the Accommodation might use the exemption. J.A. 41–42.

Little Sisters—but not the Agencies—denies that the Religious Rule permits an employer to invoke the exemption when the Accommodation would resolve a conflict with RFRA. LS Opp’n at 34–36, ECF No. 255-1. That assertion cannot be squared with the rule, which makes the Accommodation only a voluntary alternative to the exemption. 45 C.F.R. § 147.131(c)(2). The Religious Rule’s preamble also contradicts Little Sisters’ position, explaining that the Accommodation is “optional for entities that are otherwise also eligible for the expanded exemptions” and remains “an option that exempt entities can choose.” J.A. 34. And the exemption is available to an entity that objects to any of “establishing, maintaining, providing, offering, or arranging” for payment for contraceptive coverage. 45 C.F.R. § 147.132(a)(2).

² The Moral Rule shares this flaw. *Contra* Fed Opp’n at 11 n.4. Those with moral objections to covering contraception can claim the exemption even if an alternative, such as the Accommodation, would resolve any objection.

Next, the Religious Rule is not limited to instances in which compliance with the mandate or the Accommodation imposes a substantial burden, Pls.’ Mem at 15, which is a predicate for any RFRA violation, 42 U.S.C. § 2000bb-1(a). That requiring coverage of contraception, or monetary penalties for refusing to do so, *can* impose a substantial burden on religious exercise, *see* Fed. Opp’n at 12; LS Opp’n at 20, says nothing about whether the Religious Rule reasonably targets those cases. Little Sisters misunderstands this problem as just a failure to require proof of a RFRA violation. LS Opp’n at 19–20. Omitting the substantial burden requirement, however, expands the availability of the exemption beyond RFRA violations and so divorces the Religious Rule from its purpose.

The Religious Rule’s inclusion of publicly traded corporations accomplishes a similar unreasoned expansion. Whether RFRA applies to publicly traded corporations reflects an interpretation of a statute that the Agencies do not administer. Courts have the last word in such a case. *Epic Sys. Corp. v. Lewis*, 138 S. Ct. 1612, 1629 (2018). Therefore, the Agencies’ legal conclusions about whether RFRA covers publicly traded companies must, at least, make sense under the relevant precedent. It is not enough that the Religious Rule’s legal conclusions about RFRA’s application to publicly traded companies can be “discerned.” Fed. Opp’n at 12–13. That may suffice when an agency makes a factually-informed policy judgment, *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016), but that is not the posture here.

Against the proper standard, the Agencies have not justified extending the Religious Rule to publicly traded corporations. The Agencies concluded that RFRA applies to those entities solely because 1 U.S.C. § 1 defines person to include corporations. J.A. 27. Yet that rationale was not, by itself, sufficient for the Supreme Court to extend RFRA even to closely held companies. *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 705–09 (2014); *see also* Pls.’

Mem. at 16. And the Religious Rule made the additional leap from closely held corporations to publicly traded corporations based on 1 U.S.C. § 1 alone even though *Hobby Lobby* expressed doubt about a publicly traded company having religious beliefs for purposes of RFRA. *Id.* at 717. Without citing *any* authority, the Religious Rule decided that this uncertain legal question actually is a “matter of well-established State law.” J.A. 27 & n.61 (citing only the Agencies’ expectations). The Agencies know of no publicly traded company for which the mandate presents a problem under RFRA, Fed. Opp’n at 13, but that only further signals that the Religious Rule is not addressed to actual RFRA violations. Finally, the Agencies insist that even if they misinterpreted RFRA, they still could have exercised discretion under the Women’s Health Amendment to arrive at the same conclusion. Fed. Opp’n at 13. Agency action is judged only on the reasons actually given, *SEC v. Chenery*, 318 U.S. 80, 88 (1943), and regardless there is nothing in the record justifying such a significant expansion of the exemption as a policy choice.

Nor does the Religious Rule provide any mechanism to evaluate the sincerity of an objector’s religious belief. Omitting such a mechanism will be inconsequential, according to defendants, because employees have existing ways to challenge the sincerity of their employer’s religious beliefs if needed. Fed. Opp’n at 13–14; LS Opp’n at 20–21. Even if employees may rely on the Public Health Service Act, the Internal Revenue Code, or ERISA to recoup wrongfully withheld care, J.A. 23, that the Religious Rule outsources the responsibility for ensuring compliance with RFRA further exhibits that the rule itself makes no effort to limit its effect to where the mandate and RFRA actually collide.

The Agencies’ inattentiveness to actual conflicts is especially unreasonable because unnecessary expansions of the exemption will lead to significant harm. The Guidelines still

include contraception as a necessary form of care, J.A. 312-A, but women working for an employer who claims the exemption will lose coverage. Without that coverage, contraceptive care becomes harder to access. J.A. 434. Each way the Religious Rule extends beyond actual conflicts, then, causes significant harm. That harm demands some justification.

Whether the Religious Rule resolves *some* RFRA violations is immaterial to whether the rule reasonably targets only those violations, and it does not make the rule's over-expansiveness harmless. *Contra* Fed. Opp'n at 27; LS Opp'n at 21. Yet as it is, the Religious Rule is independently arbitrary and capricious because the Agencies failed to adequately justify that the Religious Rule resolves *any* actual RFRA conflicts. RFRA is a remedial statute that the Agencies do not administer, giving courts final say over its meaning. *See Epic*, 138 S. Ct. at 1629 (“[O]n no account might we agree that Congress implicitly delegated to an agency authority to address the meaning of a second statute it does not administer.”). So a rule promulgated to remedy RFRA conflicts must be guided by judicial decisions about what RFRA prohibits. That the Agencies can exercise their rulemaking discretion to resolve RFRA violations, as *Little Sisters* held, does not free them to decide what violates RFRA independent of the relevant judicial decisions.

While the Agencies insist that the Religious Rule discussed the relevant legal authority and issues “at length,” Fed. Opp'n at 14, they overstate matters. As to substantial burden, the Agencies made no effort to reconcile their position with the overwhelming contrary case law, including what was then the only post-*Zubik* appellate decision. *Real Alternatives, Inc. v. Sec'y Dep't of Health & Human Servs.*, 867 F.3d 338, 356 n.18 (3d Cir. 2017) (concluding that the Accommodation does not impose a substantial burden). Rather, the Agencies cited the one outlier case and moved on. J.A. 11 (citing an Eighth Circuit decision concluding that the Accommodation imposes a substantial burden, but none of the other eight appellate decisions

ruling differently). Thus, the problem is not that the Agencies have a different view than that of the States, but instead that the Agencies arrived at their conclusion without even grappling with the contrary judicial consensus. Agencies are not at liberty to disregard court decisions in such a way. *See Bastardo-Vale v. Attorney Gen. United States*, 934 F.3d 255, 259 n.1 (3d Cir. 2019) (*en banc*).

Beyond that, the Agencies' reliance on RFRA as the impetus for the Religious Rule also means that if now, in the Court's view, the rule is not needed to remedy any conflicts, the rationale furnished for the Religious Rule does not exist. That is the case here, and it separately makes the Religious Rule arbitrary and capricious. For reasons this Court has already given, *Pennsylvania v. Trump* ("Pennsylvania I"), 351 F. Supp. 3d 791, 821–27 (E.D. Pa. 2019), *rev'd and remanded on other grounds*, and which the Third Circuit has affirmed, *Pennsylvania v. President* ("Pennsylvania II"), 930 F.3d 543, 572–74 (3d Cir. 2019), *rev'd and remanded on other grounds*, the status quo before the Religious Rule did not violate RFRA. The Supreme Court did not reach this issue, *Little Sisters*, 140 S. Ct. at 2382, and thus did not disturb the reasoning in either opinion.

This Court's earlier analysis was, and remains, correct. Indeed, the Agencies now recognize that even with the exemption, "an employer seeking to provide insurance that excludes coverage for contraceptives will in fact need to communicate that direction to their insurer or [third party administrator]." Fed. Opp'n at 13. The Agencies' point confirms what the States have argued all along: the Accommodation does not "trigger" the provision of contraceptive coverage and so does not impose a substantial burden on religious exercise. The obligation to provide coverage lies with the insurer and invoking the Accommodation only removes the employer from the equation.

B. The Agencies Failed to Provide a Reasoned Explanation for Their Reversal on the Safety, Efficacy, and Benefits of Contraception

While the Agencies had previously acknowledged the health benefits of contraception, in the rules they conclude that evidence of contraception's safety is mixed. At the outset, defendants claim that moving from a place of confidence to a place of uncertainty is not actually a changed position. Fed. Opp'n at 19; LS Opp'n at 31. Yet moving from "there is a consensus" to "there is no consensus" is a change in position, and the Agencies did not justify that change.

First, that all 18 forms of FDA-approved contraception may have side effects does not justify discounting the costs of eliminating access to contraceptive care. Fed. Opp'n at 17. No person uses all 18 forms of contraception. If, for a single person, any one of the various forms of contraception can be safely prescribed, the cost of eliminating access to that method cannot be reduced because the other 17 would not have been prescribed for that individual. Similarly, the Agencies highlight the Religious Rule's citation to studies showing side effects of contraceptive use as sufficient evidence to now doubt contraception's benefits. Fed. Opp'n at 19 (citing J.A. 17–18 & nn.28–34). But those studies relate to oral and hormonal contraceptives, which comprise just a few of the FDA-approved methods. Once more, the Agencies side-step that contraception, like any medicine, is prescribed individually. Doctors and patients can identify what contraceptive method will work for a particular person—which may not be an oral or hormonal contraceptive method.

Second, non-medical considerations informed the Agencies' medical analysis. *Contra* Fed. Opp'n at 18. The Agencies' review of the "Health Effects of Contraception and Pregnancy" included whether some forms of approved contraception are abortifacients. J.A. 18. The Agencies concluded the answer was uncertain because people define pregnancy to begin at different points based on religious beliefs. J.A. 19. The Agencies claim that they did not rely on such beliefs as

part of this medical analysis because, in the end, they did not take a position on when pregnancy begins. Yet using non-medical beliefs to manufacture a medical debate is just as arbitrary as using them to resolve a medical debate. To make matters worse, the Agencies relied on non-medical sources to suggest disagreement about when pregnancy begins despite HHS's existing definition of pregnancy as beginning at implantation. *See* 45 C.F.R. § 46.202(f).

Third, the Agencies retreated without justification from their earlier position that contraception reduces teen pregnancy. Here, the Agencies do not suggest a new evidentiary basis for the change, but instead insist that they had not previously taken a position. Fed. Opp'n at 18–19. Yet HHS' Office of Adolescent Health has embraced research showing that contraception reduced teen pregnancy. J.A. 2561.³ Although the Agencies suggest doing so was not taking a position, the difference between definitive pronouncements and embracing research is semantic at best.

Finally, the Agencies changed their position about the efficacy of contraception without discussing that contraceptive equity laws, like that of Colorado, successfully reduced both unintended pregnancy and abortion. They now deny overlooking that evidence, Fed Opp'n at 20, but the Religious Rule plainly failed to consider that evidence because it stated that no comment “point[ed] to studies showing those state mandates reduced unintended pregnancies,” J.A. 20.

C. The Agencies Provided No Reasoned Justification for the Moral Rule

The Agencies' justification for the Moral Rule is similarly lacking. Congress may not have included anything in the Women's Health Amendment specifically precluding the Agencies from creating moral exemptions to the Guidelines, *Little Sisters*, 140 S. Ct. at 2381, but

³ Whether agency action is arbitrary and capricious is judged based on information contained in the administrative record. *Camp v. Pitts*, 411 U.S. 138, 142 (1973). HHS's earlier report on trends in teen pregnancy, however, only documents HHS's prior position.

Congress's expectations matter all the same because the Agencies justified the Moral Rule as fulfilling Congress's expectations, J.A. 64. Specifically, the Agencies created that rule because, "[i]t is not clear to the Departments that, if Congress had expressly mandated contraceptive coverage in the ACA, it would have done so without providing for similar [moral] exemptions. Therefore, the Departments consider it appropriate, to the extent we impose a contraceptive Mandate by the exercise of agency discretion, that we also include an exemption for the protection of moral convictions in certain cases." J.A. 67; *see also id.* (calling the Moral Rule "consistent with the scope of exemptions that Congress has established in similar contexts"). So to the extent the Agencies unreasonably judged Congress's expectations, the Moral Rule is arbitrary and capricious. That is precisely what happened. Standard methods of statutory interpretation, the legislative record, and subsequent legislative history all unavoidably impress that Congress did not anticipate a moral exemption would be included if contraception was included in the Guidelines. Pls.' Mem. at 26–28.

D. The Agencies Failed to Consider Significant Comments

Ninety-nine percent of public comments opposed the rules. Pls.' Mem. at 29. While rulemaking is not simply about counting comments, Fed. Opp'n at 22, the "[p]resence in the record of substantial quantities of adverse comment may signal clear error of agency judgment," *Telocator Network of Am. v. FCC*, 691 F.2d 525, 538 n.106 (D.C. Cir. 1982). The Agencies, relying on *NRDC v. EPA*, 822 F.2d 104 (D.C. Cir. 1987), suggest that the volume of comments against the rules is immaterial, but that case addressed whether the weight of comments, "without more," could demonstrate that an agency's on the record fact finding was not supported by substantial evidence. *Id.* at 122 n.17. That is not the posture the here. Plus, there is far "more."

The imbalance of comments is relevant, first, because the Agencies justified the rules as responsive to comments. *See, e.g.*, J.A. 11 (explaining that the Religious Rule was needed to

respond to concerns raised in comments about the religious burden caused by complying with either the mandate or Accommodation); J.A. 59 & n.5 (noting that commenters had supported a moral exemption prior to 2017). Presenting the rules as responsive to commenters' interests without addressing that the overwhelming weight of comments opposed the rules is clear error of judgment. The error is particularly stark for the Moral Rule because the Agencies have not identified any part of the ten supportive comments expressing a non-religious moral objection to contraception.

Moreover, the Agencies did not respond to comments from the medical community that voiced concerns with many of the Agencies' medical judgments. A comment's significance may typically depend on its content rather than its author, Fed Opp'n at 22–23 (citing *City of Portland v. EPA*, 507 F.3d 706 (D.C. Cir. 2007)), but in this context the content and author of are not so easily separated. Medical comments are relevant because they come from medical experts, and a rule that espouses medical judgments, as here, is arbitrary if it fails to confront a contrary consensus from medical experts. The *en banc* Fourth Circuit just ruled another of HHS's rules was arbitrary and capricious for this very reason. *Mayor of Baltimore v. Azar*, 973 F.3d 258, 276–79 (4th Cir. 2020) (*en banc*).

Further, the Agencies claim to have responded to comments expressing a concern about the Religious Rule's effect on access to contraceptive *counseling*, Fed. Opp'n at at 24, but they do so by pointing to the Religious Rule's estimation that contraceptive *methods* are available outside employer-provided insurance plans, J.A. 21. And even that tangentially relevant answer is belied by comments about the limited capacity of state- and federally-funded programs—an issue raised in yet another set of comments that the Agencies did not answer. Several commenters identified funding shortages for Title X clinics as reason to doubt that those clinics

could meet any increased need caused by the rules. *See* Pls.’ Mem. at 29–30 (collecting comments). The Agencies claim to have discussed those comments, Fed. Opp’n at 23–24 (citing J.A. 16), but in fact discussed limits on patient eligibility for Title X clinics. Whether Title X clinics have funding to absorb any increased demand has different—and broader—implications than whether only some of those who lose coverage will be eligible to go to a Title X clinic.

Finally, this Court has not definitively ruled on the adequacy of the Agencies’ response to significant comments. *Contra* Fed. Opp’n at 23; LS Opp’n at 32. This Court’s earlier decision reached only the few comments submitted with the States’ preliminary injunction motion, which was filed before the administrative record was available. *See Pennsylvania I*, 351 F. Supp. 3d at 811–12. The Supreme Court has not reached this question either. *Contra* LS Opp’n at 32. The Supreme Court said only as a descriptive matter that the Agencies responded to comments between the interim and final rules. *Little Sisters*, 140 S. Ct. at 2378.

E. The Agencies’ Regulatory Impact Analysis Is Arbitrary and Capricious

In the end, the Agencies concluded that the benefits of the rules outweigh their costs. While the Agencies’ balancing of the costs and benefits may be owed some deference, Fed. Opp’n at 24–2, the Agencies may not calculate the costs and the benefits in an arbitrary manner. And as the *en banc* Fourth Circuit recently explained, an agency’s estimate of the costs of its rule must be based on “figures that make at least some modicum of sense” instead of those “pulled from thin air.” *Baltimore*, 973 F.3d at 282 (cleaned up). That did not happen here.

First, the rules omitted the dependents of policyholders that use the individual exemption in the estimate of people who will lose coverage. Both defendants incorrectly claim that group was excluded because the Agencies assumed that dependents of people who claim the individual exemption will share the faith of the policyholder, Fed Opp’n at 25; LS Opp’n at 33, but defendants cite nothing in the rules reflecting that assumption.

Second, in the interim Religious Rule, the Agencies had assumed that 1,027,000 people received insurance from an entity that had been using the Accommodation before the Religious Rule, and that 75% of them, or about 770,000, received insurance through one of 100 religious hospitals or health systems the Agencies believed would continue using the Accommodation despite the new rule. J.A. 127. The Agencies assumed the remaining 25%, or roughly 257,000 people, worked for one of 109 entities that the Agencies expected would take advantage of the exemption. J.A. 127. In the final Religious Rule, the Agencies assumed that in fact 2,907,000 people received insurance from an entity that previously used the Accommodation. J.A. 42. Despite the almost threefold increase from the interim rule, the Agencies still assumed that those 2.9 million people all received insurance through the same 209 entities identified in the interim Religious Rule and that 75% of them—or 2,180,000 people—received coverage from one of the 100 religious hospital or health systems that would stick with the Accommodation. J.A. 42.

Adhering to that number of entities and assumed distribution, however, meant that the 100 hospitals and health systems added, on average, 7,000 policyholders each in just two years. The Religious Rule makes no effort to explain sticking to its earlier assumptions despite the extraordinary implications. And assuming that the number of entities supplying coverage to those people was still just 209 despite the near threefold increase in total people covered allowed the Agencies to keep to their assumption that the 100 hospitals and health systems provided coverage to 75% of all people. J.A. 42. Of course, it is far more plausible that more than 209 entities had been using the Accommodation all along. But if the hospital systems in fact were just 100 of 409 total entities, for example, that used the Accommodation then assuming those hospitals continue to insure 75% of all people covered by an accommodated plan is not defensible. In this way, the number of entities assumed to have used the Accommodation prior to

the rules affected the Agencies' impact analysis. But even if that number was meaningless, as the Agencies propose, Fed Opp'n at 25, it is unclear why using meaningless, unexplained numbers makes the impact analysis *less* arbitrary.

Third, the Agencies assumed that the 100 religious hospitals and health systems that previously used the Accommodation would continue to do so based on public statements made *before* an exemption was available to any of them. J.A. 41 n. 87. And immediately after citing those public statements, the Agencies conceded that some of the hospitals and health systems may make use of the exemption. J.A. 42. The context of these statements, rather than the forum in which they were made, undermines their value. *Contra* Fed. Opp'n at 25–26; LS Opp'n at 33.

Fourth, after estimating that 379,000 women receive insurance coverage from an entity reasonably likely to use the exemption, the Agencies cut that estimate by two thirds because they assumed the majority of the employers that started covering contraception because of the mandate were not employers with religious objections to covering contraception. J.A. 45–46; *see also* Pls.' Mem. at 32–33. That very same assumption, however, was part of the Agencies' initial estimate that only 379,000 women received insurance coverage through an entity likely to use the exemption. Indeed, the Agencies decided in the first place that only 6% of employers that did not cover contraception before the mandate had not done so for religious reasons. J.A. 44 & n.103. The unreasonable course here was using the same assumption twice: once on the front end to lower the number of women who receive insurance from an entity likely to use the exemption, and once more on the back end to cut that figure down to a third.

II. The Rules Are Contrary to Law

A. The Religious Rule Violates the Establishment Clause

While all agree that the Establishment Clause does not forbid the government from accommodating religious beliefs, the Establishment Clause does limit how far the government

may go to do so, and what consideration must be given to who will be harmed along the way. For one, any accommodation may not foster religion. *Corp. of Presiding Bishop of Church of Jesus Christ of Latter-day Saints v. Amos*, 483 U.S. 327, 334–35 (1987). For another, any accommodation must be measured so as not to “override other significant interests,” *Cutter v. Wilkinson*, 544 U.S. 709, 722 (2005), or provide any individual or entity an absolute right to insist others conform to the accommodated entity’s religious beliefs, *Estate of Thornton v. Caldor, Inc.*, 472 U.S. 703, 710 (1985).

Contrary to the defendants’ position, Fed. Opp’n at 33–34; LS Opp’n 39–40, the Establishment Clause applies even when the government removes government-created burdens. Defendants rely on *Amos* to argue otherwise, but since *Amos* the Supreme Court considered an Establishment Clause challenge to the Religious Land Use and Institutionalized Persons Act (RLUIPA) after that statute had been used to relieve “exceptional government-created burdens on private religious exercise.” *Cutter*, 544 U.S. at 720. Using RLUIPA to relieve government-created religious burdens, the Court resolved, was constitutionally permissible only because RLUIPA requires that whatever accommodation is provided also accounts for “the burdens a requested accommodation may impose on nonbeneficiaries.” *Id.*; accord *Hobby Lobby*, 573 U.S. at 729 n.37.

Here, even though the Religious Rule exempts employers from a regulatory obligation, it may not foster a religious preference and must take into account harms to third parties. But instead the new exemption causes women to lose contraceptive coverage even though there is an alternative that in most, if not all, instances removes barriers to religious exercise while avoiding the costs that women would otherwise bear. An accommodation that goes beyond what might

plausibly be construed as simply removing a barrier is a preference for religious interests over others, as in *Caldor*.

Due to that preference, 126,400 women will lose coverage for necessary care. The relevant baseline for assessing the harm the Religious Rule causes is what coverage women are entitled to without that rule. *Contra* Fed. Opp’n at 33. Having adopted guidelines recognizing that contraceptive care is a preventive service for women, the Agencies cannot subsequently issue a rule to accommodate religious beliefs without considering the very women Congress has entitled to the coverage identified in those guidelines.

Little Sisters argues that if the rules violate the First Amendment then the mandate must too because some religious organizations, but not others, would be exempt from the mandate. LS Opp’n at 15–17. That argument is far afield of this case, and, in any event, is not properly directed at the mandate but at prior agency actions that created other exemptions. Nor is *Our Lady of Guadalupe School v. Morrissey-Berru*, 140 S. Ct. 2049 (2020), relevant here. That case concerns religious education at religious schools. As the Court stressed, “religious education and formation of students is the very reason for the existence of most private religious schools” and so “[j]udicial review of the way in which religious schools discharge those responsibilities would undermine the independence of religious institutions.” *Id.* at 2055. Providing insurance coverage to its employees does not go to the very reason any religious entity exists.

B. The Rules Create an Unreasonable Barrier to the Availability of Appropriate Medical Care in Violation of Section 1554 of the Affordable Care Act

Section 1554 of the Affordable Care Act bars the Secretary of HHS from issuing any regulation that “creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care.” 42 U.S.C. § 18114(1). The rules do just that by making it more difficult for women to obtain care that the Guidelines consider essential. J.A 312-A (calling

contraception “necessary for women’s health”); J.A. 433–34 (explaining that availability of insurance without cost-sharing requirement promotes access to contraceptive care).

Section 1554 indeed provides a standard for judicial review. *Contra* Fed. Opp’n at 35 (citing *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 410 (1971)). Just recently, two appellate courts sitting *en banc* considered whether agency action was not in accordance with law because it violated Section 1554. *Baltimore*, 973 F.3d at 288–92; *California by & through Becerra v. Azar*, 950 F.3d 1067, 1091–95 (9th Cir. 2020) (*en banc*). The Fourth Circuit concluded that the agency action in that case—an HHS rule instructing doctors that receive Title X funds not to refer patients for an abortion—unreasonably impeded access to medical care. *Baltimore*, 973 F.3d at 288. Likewise, the rules here directly interfere with access to care by preventing a patient from receiving insurance coverage that facilitates access to that care. J.A. 433–34. That the rules act through employers does not change the barriers they erect.

Defendants principally rely on the second case, *California*, see Fed Opp’n at 35–36; LS Opp’n at 43–44, a Ninth Circuit decision ruling that the same agency action at issue in *Baltimore* did not violate Section 1554. But the Ninth Circuit explained that the challenged rule only “ensure[s] government funds are not spent for an unauthorized purpose,” which it distinguished from what Section 1554 prohibits: “direct interference with certain health care activities.” *California*, 950 F.3d at 1094 (citing *Rust v. Sullivan*, 500 U.S. 173, 200 (1991)). No matter which court was right about how Section 1554 applies to HHS’s Title X regulation, the Ninth Circuit’s reasoning is inapplicable here as the rules are not restrictions on the use of government funds but instead directly interfere with contraceptive health care.

Recognizing the unreasonable barrier that the rules erect would not impose any affirmative obligation on the government. *Contra* Fed. Opp’n at 36. The Women’s Health

Amendment requires insurers to cover the essential forms of care that the Guidelines identify, which include contraceptive care. The rules operate against that baseline. Because of the rules alone, over 124,000 women will lose insurance coverage for a form of care that the Guidelines define as essential. That is an unreasonable barrier.

C. The Rules Violate the Equal Protection Provisions of the Fifth Amendment

The ACA's preventive service section identifies several categories of care that group insurers must cover. Of those categories, one is specific to women. 42 U.S.C. § 300gg-13(a)(4). That is the only category of care for which the Agencies have created exemptions. By subjecting just women's care to lesser protection, the rules embody the Agencies' discriminatory treatment.

That discrimination is not incidental—it is the very design of the rules to target only the part of the preventive service provision that applies exclusively to women. In fact, the President's Executive Order that preceded the rules specifically directed the Agencies to consider issuing regulations that address objections to those services provided under the Women's Health Amendment and said nothing about any other services mandated by the ACA or any other law. J.A. 167. And the Women's Health Amendment was enacted to address the “fundamental inequity in the current system” and to stop the “punitive practices of insurance companies” toward women. J.A. 2437, 2378. Then-existing preventive services guidelines were not written with women in mind and so left out certain essential services for women. J.A. 313–561.

Because the rules discriminate on the basis of sex, the sex-based classification must be able to survive intermediate scrutiny. *United States v. Virginia*, 518 U.S. 515, 533 (1996). The *classification* itself needs “an exceedingly persuasive justification,” *Alabama ex rel. T.B.*, 511 U.S. 127, 137 (1994), which requires showing the classification “serves important governmental objectives” and that its discriminatory means are “substantially related to the achievement of those objectives.” *Virginia*, 518 U.S. at 533. So, to say that there are good reasons to exempt

certain insurers from their obligations to cover contraception for women, *see* Fed. Opp’n at 38; LS Opp’n at 42, leaves the relevant issue—the reason for the sex-based distinction—unaddressed. Contraceptive care is not “the sole form of health care that implicates religious concerns.” *Grote v. Sebelius*, 708 F.3d 850, 866 (7th Cir. 2013). Without any explanation for why the sex-based classification is justified, the rules cannot survive intermediate scrutiny.

D. The Rules Violate Section 1557 of the ACA and Title VII of the Civil Rights Act

Because the rules create exemptions only from requirements to cover women’s preventive services, *supra* Section. II.C, the rules also violate Section 1557 of the ACA and Title VII of the Civil Rights Act, each of which prohibits sex-based discrimination. And because the rules *treat* women differently, the Agencies’ arguments about a disparate *impact* theory are beside the point. *See* Fed. Opp’n at 40–41.

So, too, are arguments about the absence of an employment relationship between the Agencies and the States, which has no bearing on whether the rules are “in accordance” with Title VII’s prohibition of sex-based against employees. *Contra* Fed. Opp’n at 39–40.⁴ Application of Title VII here is no different than in *New York v. U.S. Department of Health & Human Services*, 414 F. Supp. 3d 475 (S.D.N.Y. 2019), a case vacating a separate HHS rule. In *New York*, the court reviewed an HHS rule that interpreted several statutes pertaining to conscience exemptions in medical contexts. *Id.* at 496. The rule defined “discrimination” for which an employer may be liable as including the failure to accommodate an employee’s religious beliefs, even if an accommodation would cause undue hardship to the employer. *Id.* at

⁴ At most, the lack of an employment relationship between the States and the Agencies matters insofar as Title VII itself does not provide the States recourse for the conflict between the rules and that statute. 42 U.S.C. § 2000e-5. For this reason, at a minimum, Title VII’s enforcement mechanism is not an alternative remedy that forecloses judicial review under the Administrative Procedure Act. *Contra* Fed. Opp’n at 40.

513–14. For that reason, an HHS grant recipient could be liable to the agency for actions that complied with Title VII. *Id.* at 514. Similarly, an employer could be liable for discrimination under the rule even if the employer offered a reasonable accommodation for the employee’s religious beliefs; that, too, contradicted Title VII. *Id.* at 514–15. Because the rule regulated employment relationships inconsistent with Title VII, the rule was not in accordance with the law. *Id.* at 536–37. Here, the rules allow employers to single out women for lesser treatment by allowing employers to remove health care coverage only from their female employees’ benefit packages. In that way, they authorize conduct that Title VII prohibits. Pls.’ Mem. at 40–43.

Little Sisters’ final argument—that the States’ are using Title VII as a backdoor means of creating a nationwide contraceptive mandate—once more ignores the applicable baseline. The ACA creates a right to coverage for several forms of preventive care. For women, the ACA and the Guidelines work in concert to create a right to contraceptive coverage. The issues here revolve around rules that single out coverage of that care for exemptions, not whether that coverage must be provided in the first instance.

Section 1557 also prohibits discrimination on the “ground prohibited under . . . title IX of the Education Amendment of 1972 (20 U.S.C. § 1681 et seq.).” 42 U.S.C. § 18116(a). The “ground” is discrimination on the basis of sex. 20 U.S.C. § 1681(a). That Congress has allowed educational institutions controlled by religious organizations to discriminate on the basis of sex when compelled by a religious tenet, 20 U.S.C. § 1681(a)(3), does not speak to what “ground” of discrimination Title IX prohibits. *Contra* LS Opp’n at 44. One district court has held that Section 1557’s reference to the “ground prohibited” under Title IX includes the religious exemption, but its reasoning should not be followed. That court read Section 1557 to allow sex-based discrimination by a religious institution solely because Section 1557 uses the phrase “et seq.” in

a parenthetical citation for where Title IX is codified. *Franciscan Alliance, Inc. v. Burwell*, 227 F. Supp. 3d 660, 690 (N.D. Tex. 2016). But a citation for where to find Title IX in the U.S. Code, however styled, does not change that Section 1557 prohibits discrimination on the “ground” identified in Title IX: on the basis of sex.

III. The States Have Standing

By now, the States’ standing is settled. The rules “inflict a direct injury upon the States by imposing substantial financial burdens on their coffers.” *Pennsylvania I*, 351 F. Supp. 3d at 807. With the rules having just taken effect for the first time, those harms are impending, and the States need not wait for the women who will lose coverage to start turning to state-funded programs to bring suit. *Id.* The Third Circuit agreed that the States have established a certainly impending injury as the rules themselves anticipate that women in Pennsylvania and New Jersey will lose contraceptive coverage. *Pennsylvania II*, 930 F.3d at 562. Those women will turn to state resources. *Id.* at 563.⁵

Nevertheless, the Little Sisters continues to press rejected arguments. *See* LS Opp’n at 7. The absence of a particular person who will turn to state-funded resources does not defeat standing. *Pennsylvania II*, 930 F.3d at 564. Nor is the record on which the Third Circuit previously assessed the States’ standing insufficient now. The record reveals that the rules will deprive women of insurance coverage, causing women to rely on state programs. *Id.* at 562–63. These injuries are as real now as they were earlier.

Redressability is no more an issue than injury-in-fact. Little Sisters suggests that no matter what happens to the rules, the Guidelines themselves now contain the rules’ exemptions

⁵ At oral argument, Justice Thomas raised the States’ standing. Transcript of Oral Argument at 31–32, 55–58, *Little Sisters of the Poor Saints Peter and Paul Home*, 140 S. Ct. 2367 (2020) (Nos. 19-431 & 19-454). If the Court doubted the States’ standing, it would have had no choice but to rule on that jurisdictional issue.

and will live on independent of the rules. LS Opp’n at 9–10. But the Guidelines do not independently create exemptions from their otherwise generally applicable requirements. They merely reflect the rules’ direction that certain employers are exempt. The rules themselves “delineat[e] what exemptions and accommodations apply if [the Health Resources and Services Administration] lists contraceptives in the Guidelines.” J.A. 8; *see also* J.A. 88–89. Indeed, the rules’ legal conclusion was that the Agencies “are legally authorized to exempt certain entities or plans from a contraceptive Mandate if HRSA decides to otherwise include contraceptives in its Guidelines.” J.A. 10; *accord* J.A. 61. Exemptions from the Guidelines always have been the work of the Agencies, not HRSA; prior exemptions resulted from regulations the Agencies promulgated to “guide HRSA in exercising its discretion.” J.A. 3; *see also* J.A. 6 (“The Departments defined the scope of the exemption to the contraceptive Mandate when HRSA issued its Guidelines for contraceptive coverage in 2011, and then amended and expanded the exemption and added an accommodation process in multiple rulemakings thereafter.”). Little Sisters incorrectly cites the Supreme Court for the conclusion that the Agencies’ regulations and HRSA’s guidelines each “may limit the other’s effects,” LS Opp’n at 10, when in fact the Supreme Court observed only that the Guidelines are subject to any lawfully-created agency exemption, *Little Sisters*, 140 S. Ct. at 2374. The exemptions now contained in the Guidelines merely reflect the Agencies having limited the Guidelines’ effect.

Separately, no injunction obtained against the mandate is an obstacle to relief. *Contra* LS Opp’n at 10–11. Women insured by an entity covered by an injunction at the time the rules were promulgated were excluded from the Agencies’ estimate of the rules’ impact. J.A. 40–41. And existing injunctions do not resolve the rules’ application to entities that need not show a right to relief under RFRA. Nor does the injunction entered in *DeOtte v. Azar*, 393 F.Supp. 3d 490 (N.D.

Tex 2019) pose a redressability problem. For one, that injunction is currently on appeal. *DeOtte v. Azar*, No. 19-10754 (5th Cir.). And even if the class-wide injunction, which suffers from both imprecision and over breadth as to the class members, survives, that injunction does not apply to health plans from colleges and universities or to the Moral Rule.

IV. Little Sisters' Other Arguments Should Be Rejected

Little Sisters also attacks the contraceptive mandate on two grounds that, it argues, deprive the States of any redressable injury. These arguments are well beyond the scope of this case, which is not about any challenge to the mandate. They also are well outside the purpose of the Little Sisters' intervention, which is "defending the portions of the religious exemption [interim final rule] that apply to religious nonprofit entities." *Pennsylvania v. President*, 888 F.3d 52, 62 (3d Cir. 2018). In any event, on the substance each argument is easily refuted.

First, Little Sisters invokes the non-delegation doctrine, which stops Congress from assigning responsibility to an agency without also providing an intelligible principle to guide the agency's exercise of its responsibility. *Gundy v. United States*, 139 S. Ct. 2116, 2123 (2019) (plurality). Only two statutes have ever failed that standard. *Id.* at 2129. There is no reason for the Women's Health Amendment to be the third. The Guidelines are to include services that are: (1) for women, (2) preventive, and (3) exclusive of services that the United States Preventive Task Force recommends. That is an intelligible principle for what the Guidelines shall include.

Second, Little Sisters reference the Appointments Clause, which requires that "Officers of the United States" are appointed by the President and confirmed by the Senate. U.S. Const. art. II, § 2 cl. 2. Little Sisters wrongly suggests that the Women's Health Amendment puts the HRSA Administrator in a position akin to an SEC administrative law judge, an office the Supreme Court recently said is subject to the Appointments Clause. *Lucia v. SEC*, 138 S.Ct. 2044, 2053 (2018). But in *Lucia*, the Court's analysis began from the premise that those judges

have “extensive powers” over the parties that come before them. *Id.* at 2049. Unlike the decisions of those judges, the Guidelines have no independent force. Congress has directed insurers to comply with the Guidelines, and compliance is defined by the Agencies. *See* 45 C.F.R. Part 147. And the Women’s Health Amendment does not charge HRSA’s Administrator with any duties; it taps HRSA, a division of HHS, to support the development of preventive health guidelines for women. Whatever else might be said about statutes that assign power to the Administrator is both outside the scope of this case and, in any event, inapposite.

V. The Rules Must Be Vacated

Finally, the remedy here is to “set aside” the rules in all applications. 5 U.S.C. § 706(2). Given the harms that the States will experience because of the rules, there was no warrant even at the preliminary injunction stage for the rules not to be enjoined nationwide. *Pennsylvania I*, 351 F. Supp. 3d at 830–35. There is even less now that the case has arrived at the final judgment stage. At this stage, “courts invalidate—without qualification—unlawful administrative rules as a matter of course, leaving their predecessors in place until the agencies can take further action.” *Pennsylvania II*, 930 F.3d at 575.

The Supreme Court recently confirmed as much. *Dep’t of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1916 n.7 (2020). In one of the cases consolidated before the Court in *Regents*, the district court had entered final judgment for the plaintiffs and vacated the challenged agency action. *Nat’l Ass’n for the Advancement of Colored People v. Trump*, 315 F. Supp. 3d 457, 473–74 & n. 13 (D.D.C. 2018). Affirming that relief obviated any need to consider the propriety of nationwide injunctions entered in the remaining consolidated cases. *Regents*, 140 S. Ct. at 1916 n.7. The implication, of course, is that the two forms of relief are co-extensive.

Nor is there any basis to sever certain parts of the rules. When only some parts of a regulation are unlawful, they may be set aside and the rest of the regulation saved. *See K Mart*

Corp. v. Cartier, Inc., 486 U.S. 281, 294 (1988). But severance is possible only if a regulation's flawed elements are confined to discrete provisions. The principal defects here—the failure to craft rules that reasonably respond to a reasonably identified problem and the failure to conform with the law—infect the rule entirely. Neither defendant identifies a part of either rule that could be salvaged if the States prevail. Sure enough, no aspect of the rules is spared from all of flaws in the rationale the Agencies have offered for the rules, the Agencies' inadequately explained change of position, the rules' constitutional conflict, and the rules' failure to be in accord with federal statutes. And finally, there is no waiver on this point. *Contra* LS Opp'n at 36. Defendants have raised severability in their respective opening briefs. The States are now responding.

CONCLUSION

For the reasons above, the States' Motion for Summary Judgment should be granted, defendants' motions for summary judgment should be denied, and the rules should be vacated.

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